of thermoplastic polymers and thermosetting polymers, and the coating being non-continuous on the medical device.

Applicants traverse the rejection.

Porter et al., US 5,766,204

Porter et al. describe a curable fiber composite stent, which upon formation in situ inside a selected region of a body lumen, serves to support the lumen without significant obstruction to blood flow. The stent is made up of a biocompatible fibrous material which is coated, impregnated, filled, or otherwise treated with a curable material so that the fiber composite can be suitably shaped to support a portion of a body lumen and then cured to maintain the shape.

To reduce the risk of toxicity from the curable material prior to curing, the stent can further include a layer of a biocompatible material which encapsulates the curable fiber composite and serves as a barrier between the stent and any circulating blood, and between the stent and the lumen wall. Suitable biocompatible materials which can be used for this purpose include, but are not limited to, silicones, waxes, polyacrylamides, polyethylenes, polystyrenes, polypropylenes, polyolefins, polyurethanes and other thermoplastic elastic polymers. In one embodiment of the invention, a multifilament fiber (e.g., cotton or carbon) is saturated with UV curable material and then encapsulated within a polyethylene terephthalate (PET) shrink tubing.

Muni, US 6,273,878

Muni describes an improved catheter shaft to reduce cost and improve performance. In one aspect, a small notch is fabricated into a catheter tube by a nonlaser process such as electric discharge machining (EDM) or mechanical grinding. This notch in the catheter tube is necessary for fluid communication between the catheter lumen and a balloon or other element in communication with the tube. Use of a nonlaser process reduces the costs of fabrication while ensuring a high degree of structural integrity. *In another aspect, a method is provided to produce a nonuniform polymer coating on a catheter shaft to reduce friction and to maintain a catheter with a low profile.* In another aspect, the catheter is provided with a radiopaque marker which is more visible and is more effective at identifying the location of a

balloon. The marker is moved closer to a distal balloon by placing it within an adhesive taper adjacent the balloon.

Muni describes application of the non-uniform coating by sputter-coating the shaft or tubular body with a polymeric material to *reduce friction* between the catheter and blood vessels and *produce a lubricious, nonuniform coating* on the tubular body. Muni states that "nonuniform" refers either to a coating that is variable in thickness along the circumference or length of the body, or to a coating which covers the body in some areas but not at all in others.

Muni goes on to state that sufficient lubricity can be achieved with a nonuniform or even intermittent, sporadic coating, while simultaneously maintaining a low profile.

The Office Action asserts that based on the teachings of Muni, it would have been obvious to modify Porter, et al. with a non-continuous coating since said modification is well known in the art and therefore an obvious design alternative.

Applicants disagree.

First of all, Porter et al. describes biocompatible coatings for ***stents*** impregnated with a curable to reduce the risk of toxicity. Muni suggests nonuniform coatings for ***catheter shafts*** to reduce friction while maintaining low profiles. While Muni suggests a balloon in combination with a catheter shaft, there is no suggestion to coat the balloon.

Thus, the combination of a nonuniform coating on a catheter shaft and a coating for a composite stent, does not lead one of skill in the art to a noncontinuous protective coating for a ***balloon***.

Furthermore, Applicants submit that there must be some suggestion or motivation to combine these references. Finding that suggestion or motivation to combine prior art references is supplied by nature of problem to be solved or knowledge of person of ordinary skill in art.

To prevent the use of hindsight based on the invention to defeat patentability of the invention, the courts have required an examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. See *In re Rouffet* 47 USPQ2d 1453, 1457 (Fed. Circ.,

1998).

In that case, the court identified three possible sources for a motivation to combine references including the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. The court also stated that the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness. *In re Rouffet* at 1458.

Independent claim 1 of the above-referenced patent application is directed to a medical balloon having *a substantially uniform noncontinuous protective surface coating* and independent claim 3 of the above-referenced patent application is directed to a dilatation balloon having a *noncontinuous protective coating*. The protective surface coating is applied to reduce the likelihood of scratches, abrasions or even punctures which can occur during handling and storage of balloons. Such scratches, abrasions and punctures may ultimately lead to balloons which fail to inflate properly, balloons which burst prematurely, balloons which overexpand, and so forth.

The present specification discusses these problems in various places throughout. For example, balloon catheters are produced from materials which can withstand high pressures, even at low film thicknesses. However, such materials tend to be harder and to be scratch and puncture sensitive. See page 1, lines 23-31.

Scratches, abrasions and even punctures can occur during handling and storage of the devices, or during use. Stents or other objects may scratch or puncture the balloon. Friction between the device and the vessel through which it is being passed can result in failure of the balloon at the weakened points that result from scratches, abrasions or punctures. ***Lubricious coatings can reduce the friction between the device and the vessel wall, but provide only limited protection and do not really address the problem of scratches, abrasions and punctures.*** See page 2, lines 1-7.

Balloon failure at points of abrasions, scratches or punctures can be a problem during inflation. The balloon may prematurely burst, or the point at which the abrasion, scratch or puncture is located tends to be weaker, and when inflated, will have a tendency to over expand at that point, leading to over extension or bulging in the balloon wall at the weakened point. These bulges can in turn cause damage to blood vessels, for instance. Over inflation is also a

problem during stent delivery.

More compliant materials tend to be more scratch and puncture resistant, but do not provide the strength required to withstand the pressures used in some of these procedures. Non-compliance which is the ability to resist expansion beyond a predetermined size upon pressure, and to substantially maintain a profile, is required of balloon catheters, especially those utilized in small vessels. Excessive expansion of more compliant materials can result in the rupture or dissection of blood vessels. See page 2, lines 10-21.

Applicants submit that encapsulating a curable curable fiber composite stent with a biocompatible coating to reduce the risk of toxicity as suggested by Porter et al., is quite irrelevant to the problem solved by the present invention.

Applicants submit that Muni suggests several improvements to a catheter shaft, not to a balloon, the improvements of which include application of a nonuniform polymer coating on a catheter shaft ***to reduce friction and to maintain a catheter with a low profile***, a problem not relevant to that which is addressed by the present invention. Muni states at col. 1, lines 46-55 that the profile is often a concern for catheters because of the small space in which the catheters will be inserted. In addition, Muni states, because catheters must be passed through a tortuous blood vessel network to reach the intended treatment site, it is desirable that the catheters be substantially frictionless to reduce harmful contact with blood vessel walls. Catheters therefore are generally provided with a coating that will increase lubricity of the catheter. These coatings add additional, undesired size to the catheter. Thus, there is a need for a substantially frictionless catheter surface which does not add significant profile to a catheter tube. See col. 1, lines 46-55. Furthermore, while Muni describes the use of a balloon in combination with the catheter shaft, there is no suggestion to employ that coating on the balloon.

Thus, the combination of Porter et al. with Muni does not suggest the protective coatings as described and claimed by the present invention, and the nature of the problem addressed by the present application, is different from both the nature of the problem addressed by Muni and the nature of the problem addressed by Porter et al.. Thus, there would be no motivation or expectation of success in the combination of Muni with Porter et al. to add a noncontinuous coating to medical devices such as balloons to reduce the risk of scratches, abrasions or punctures that can lead to problems during inflation.

Independent claims 23 and 27 further have the limitation that the coating be "substantially uniform" but noncontinuous. Applicants submit that the only application method suggested by Muni is sputter coating, and that a substantially uniform coating cannot be provided by sputter coating. In fact, Muni teaches a nonuniform coating. Porter et al. describes the stent as being encapsulated.

The examiner has further introduced Sahatjain or Wang, et al. to demonstrate that it is conventional and well known in the art to use coatings on dilatation balloons. The examiner argues that whether the coating is applied to a stent, a catheter shaft, or a catheter balloon, the coating is intended to facilitate the introduction of the particular surgical instrument into the area of application in the body.

Sahatjian describes delivery of a drug from a lubricious hydrogel coating on a balloon. Applicants acknowledge that lubricious coatings are known.

Wang et al. describes an inflatable balloon for a catheter which includes a ***coating which causes the balloon to prefer a predetermined, low profile configuration***, such as a trifold configuration when deflated. The balloon has a wall which has an exterior polymeric coating. The coating is set while the balloon is in the predetermined low-profile deflated configuration so that after inflation, the coating acts to urge the balloon to return to the low profile configuration as the balloon is deflated.

Applicants submit that combining the lubricious coatings of Sahatjian and the coatings of Wang et al. which cause the balloon to prefer a predetermined, low profile configuration with the coated composite stent of Porter et al. or the catheter shaft of Muni having a nonuniform lubricious coating, does not lead one of skill in the art to the balloons of the present invention which are coated with protective coatings of a noncontinuous nature to prevent bubbling or aneurysms in the outer protective coating if the underlying device, i.e. balloon wall, becomes damaged and allows inflation medium to escape. See page 3, lines 18-20.

Moreover, the coatings of the present invention are not present to facilitate the introduction of the particular surgical instrument into the area of application in the body as asserted in the Office Action.

Thus, the combination of references does not lead one of ordinary skill in the art to the present invention. Based on the foregoing arguments and amendments, Applicants

respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-8 and 23-29 over Porter et al. in view of Muni and (Sahatjian or Wang, et al.).

CONCLUSION

Claims 1, 3-8 and 23-29 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing arguments and amendments, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: September 27, 2002

By: _____

Lisa R. Lindquist
Registration No.: 43071

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
LRL/taf
f:\wpwork\lrl\07531us_amd_20020927.doc

Marked-Up Text

MARKED UP VERSION TO SHOW CHANGES MADE

In the Claims

1. (Thrice Amended) A medical [device] balloon insertable in the body, said medical device having a substantially uniform noncontinuous protective surface coating.

27. (Amended) A dilatation balloon formed from a thermoplastic polymer, said balloon having a protective coating applied to said dilatation balloon in a substantially uniform discontinuous pattern.